510(k) Summary of Safety and Effectiveness

Date:12/14/07 K073630

JAN 11 2008

Submitter:
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Device Name:
Trade Name: BPCard
Common Name: Blood Pressure Monitor
Classification Name: System, Measurement, Blood-Pressure, Non-invasive
Classification: Class II
Panel Code: DXN
Regulation Number: 21CFR. 870.1130 Noninvasive blood pressure measurement system.

Identification of Legally Marketed (Unmodified) Device (Predicate Device):

Name of Predicate	Manufacturer	Use	510K)	Date Cleared
BPCard™	QRS Diagnostic, LLC	Blood Pressure Monitor	K031964	9/5/03

Device Description:

Indications for Use
Blood Pressure Monitor that measures blood pressure (systolic and diastolic) using the ausculatory method. The BPCard also measures heart rate.

- Patient Population: Male/Female Adults
- Environment of Use: Hospital, Clinic and Home Use
- Prescription Device by a Physician

Technological Comparison to (Unmodified) Predicate Device:

The following summary table of comparisons compares the Modified BPCard Device to the Previously Cleared BPCard (Predicate) Device.

#	Area	Modified Device	Previously Cleared Device	Same	Different
Indications for Use					
1	Patient Population	Male/Female Adult	Male/Female Adult	X	
2	Environment of Use	Hospital, Clinic, Home Use	Hospital, Clinic, Home Use	X	
Fundamental Scientific Technology					
3	Measurements taken by Device	• Systolic Pressure • Diastolic Pressure • Pulse Rate	• Systolic Pressure • Diastolic Pressure • Pulse Rate	X	
4	Measurement Method	Auscultatory	Auscultatory	X	
5	Device Components	• BPCard (PCMCIA) • Microphone Assembly • Blood Pressure Cuff • Software	• BPCard (PCMCIA) • Microphone Assembly • Blood Pressure Cuff • Software	X	
Contraindications					
6	Contraindications	No contraindications	Contraindicated in patients who are not ambulatory, have heart failure, arrhythmia or cardiac valve abnormality.		X
Sterility/Expiration Dating					
7	Sterile/Non Sterile	Non-Sterile/No Expiration Date	Non-Sterile/No Expiration Date	X	
Energy Type					
8	AC/DC	Both	Both	X	
Environmental Specifications					
9	Temperature/ Humidity/EMC Requirements	Same	Same	X	
Performance Standards					
10	AAMI SP10	Meets AAMI	Meets AAMI		X

#	Area	Modified Device	Previously Cleared Device	Same	Different
		SP10:2002	SP10:1992		
Device Hardware					
11	Dimensional and Physical Specifications	Same	Same	X	
12	PCB Board	Same	Same	X	
13	Air Coupling	Bayonet Style Connector	Luer Slip		X
14	Deflation Valve	Lee Valve	Pneutronic Valve		X
15	EMC Protection	Added measures for EMC protection to meet IEC/EN 60601-1-2:2001 as a result of other changes			X
16	Microphone Gain (Sensitivity)	X40	X10		X
17	Microcontroller Firmware	V 1.05	V 0.03		X
Materials/Components					
18	Blood Pressure Cuff	Trimline Kuff Link. Pre-amendment device.	Pymah Corporation K884421		X
19	Microphone Material	Medical Grade ABS Plastic	ABS Plastic		X
20	Microphone Cable Assembly	Dual Lumen Tubing enclosing microphone cable	No tubing enclosing microphone cable		X
Algorithms					
21	Automatic Microphone Gain Control	Available	Not available		X
22	Level Based Pulse Detection	Dynamic	Static		X
23	Pulse Proximity Evaluation	Available	Not available		X
24	Pulse Rate Calculation	Calculated from median pulse intervals.	Calculated from minimum pulse intervals.		X
Software					
25	Print Test Feature	Available	Not Available		X
26	Save and Review Tests Feature	Available	Not Available		X
27	Accept/Reject or	Available	Not Available		X

#	Area	Modified Device	Previously Cleared Device	Same	Different
	Edit Test Feature				
28	Operating System	Windows	Windows	X	
29	Software Platform	Integrated with QRS Office Medic	Stand alone software		X
30	Deflation Rate	2.5 mmHg and 5.0 mmHg	2.5 mmHg		X
31	Deflation Start	Starts when pressure and pulse detection criteria met	Starts when start button pushed		X
32	Maximum Pressure Exceeded	Test will stop and cuff will deflate	Software provides warning		X
33	Zero Function and Open and Close Valve function	Performed Automatically at start and end of test	User selects Zeroing Button and End Test Button		X
34	Calibration	User can check pressure calibration	User can check pressure calibration	X	
35	Pulse Detection Beep and Display	System does not provide audible or display indication when pulse is detected	System provides audible indication when pulse is detected and displays number of pulses		X
36	Raw Data Processing	Raw Data file can only be reprocessed with QRS development software.	Raw Data File can be reprocessed	X	
37	Pressure Display	Pressure displayed after test has begun	Pressure continuously displayed		X
38	Start of Test	Test begins after auto-zeroing completed and user begins manual inflation	Test begins after user completed manual inflation		X
39	Battery Test	OS/Computer Battery warning utilized	BPCard software provides low battery warning		X

Summary of Performance Testing:
The modified BPCard has been tested or found otherwise to comply with the following standards:

- IEC/EN 60601-1, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC/EN/UL 60601–1-2, Medical Electrical Equipment - Part 1-2: General requirements for safety - collateral standard: Electromagnetic compatibility - Requirements and Test
- ISO 10993-1, Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing
- ANSI/AAMI SP10:2002, Manual, Electronic or Automated Sphygmomanometers
- EN1060-1 "Non-Invasive Sphygmomanometers General Requirements"
- EN1060-3 "Non-Invasive Sphygmomanometers Supplementary Requirements"

Conclusions:
The results of the tests discussed above, indicate that the modified QRS Diagnostic BPCard is as safe, as effective, and performs as well as or better than the non modified device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2008

QRS Diagnostic, LLC
c/o Ms. Mary Kay Jensen
QA/RA Manager
14755 27th Ave. N.
Plymouth, MN 55447

Re: K073630
BPCard, Model Z-7000-0700
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: December 14, 2007
Received: December 26, 2007

Dear Ms. Jensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): *To be determined* K073630

Device Name: BPCard

Indications for Use:

The BPCard is a Non-Invasive Blood Pressure Monitor that measures blood pressure (systolic and diastolic) using the auscultatory method in both male and female, adult subjects. The BPCard also measures heart rate.

- Patient Population: Male/Female, Adults
- Environment of Use: Hospital, Clinic and Home Use
- Prescription Device by a Physician

Prescription Use _X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K073630